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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,357	06/09/2006	**Brendan McKeown**	08830-0286US1	9380

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EXAMINER	
HIRIYANNA, KELAGINAMANE T	
ART UNIT	**PAPER NUMBER**
1633	

NOTIFICATION DATE	DELIVERY MODE
04/27/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DBRIPDocket@dbr.com
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Office Action Summary	Application No.	Applicant(s)	
	10/501,357	MCKEOWN ET AL.	
	Examiner	Art Unit	
	KELAGINAMANE T. HIRIYANNA	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26,31-40,44 and 45* is/are pending in the application.

4a) Of the above claim(s) *1-25 and 31-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26,44 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/28/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to 01/04/2011 is entered.

Claims 33, 34, 37, 38 & 40 are amended.

Claims 27-30 and 41-43 are cancelled.

Claims 1-26, 31-40 and 44-45 are still pending.

Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is ***571-273-8300.***

Election/Restrictions

Applicant's election with traverse of Group V (Claims 26, 44 & 45) in the reply filed on 01/04/2011 is acknowledged. Applicant traverses on the grounds that all claims share a common technical feature of Sortase gene product (SNUT) as a purification tag. Applicants arguments are however found not persuasive because as indicated in the restriction requirement of 01/04/2011 the claims do not possess a corresponding technical feature. For example in claims 1-25 the base claims are generic without any requirement of a Sortase tag. Claims of group V also do not require a sortase tag as it recites it as only requiring a "vector capable of encoding a fusion protein with a sortase tag". Since most of the well known vectors are "capable" of encoding any fusion protein, the invention is obvious over prior art of any expression vector. Still further prior art indicated in the restriction requirement also teach vectors that express a Sortase protein (see also the rejections below). Thus the invention as a lacks unity under PCT rules as indicated in restriction requirement. Hence the restriction requirement as indicated in the office action of 01/04/2011 is proper and is made FINAL.

Claims 1-25 and 31-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected inventions, there being no allowable generic or linking claim. Election was made **with** traverse in the reply filed on 01/04/2011.

Claims 26, 44 and 45 are pending and under examination for the merits.

Specification

The specification is objected-to.

Specification is objected-to as it fails to list the priority documents of the Foreign Applications and the PCT from which it is derived-from on the first paragraph of the specification.

Sequences

CRF: accepted but the priority for Sequences submitted is of as of the date of fling CRF for the same

Drawings

The drawings of 06/28/04 are objected to.

Figures 4a, 4b & 4c are not discernable of their details in each of the individual lanes.

Figure 5 is not discernable of their details.

Figures 6a & 6b are not discernable of their details in each of the individual lanes.

Figures 9a, 9b & 9c are not discernable of their details in each of the individual lanes.

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application for the reasons provided above. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepare new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26, 44 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 recites "vector capable of encoding" a fusion protein. The claim is unclear for its metes and bounds. To wit, how can the claim there be a limit to capability of a vector for encoding a fusion protein or any protein?

Claim 45 recites "vector capable of encoding" a fusion protein. The claim is unclear for its metes and bounds. To wit, how can the claim there be a limit to capability of a vector for encoding a fusion protein or any protein?

Claim 26 is rejected for depending from a rejected base claim.

Claim 45 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites step (c) which is not necessary for the execution of further steps of the claimed method, hence its inclusion makes the claim indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26, 44 and 45 are rejected under 102(b) as being anticipated by Davis et al., (1999, Biotechnol. Bioeng. 65:382-388; art of record).

The above claims are drawn to a method of producing a soluble bioactive domain of a protein of interest by cloning a amplified DNA encoding said protein in to at least on

expression vector capable of encoding a fusion protein with a solubility enhancing tag comprising a SNUT tag and analyzing the expression products for solubility.

Davis teaches a method of producing soluble proteins in Escherichia coli cells as fusion proteins (entire article; abstract). Davis's fusion further possessed a N-terminal histidine tag that is used in the purification of proteins or desired protein fragments (domains) with full biological activity (entire article; abstract). Davis further uses PCR method of amplification and cloning methods for generating the expression vectors (entire article; p.383, col.1). Unless reasons to believe other wise, Davis's vectors are capable of encoding a fusion protein gene comprising a SNUT tag. Thus the rejected claims are within the scope of the Davis's disclosure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26, 44 and 45 are rejected under 35 USC 103 (a) as being unpatentable over Davis et al., (1999, Biotechnol. Bioeng. 65:382-388; art of record) in view of Ton-That et al (2000, JBC 275:9876-9881)

The above claims are drawn to a method of producing a soluble bioactive domain of a protein of interest by cloning a amplified DNA encoding said protein in to at least on expression vector capable of encoding a fusion protein with a solubility enhancing tag comprising a SNUT tag and analyzing the expression products for solubility.

Davis teaches a method of producing soluble proteins in Escherichia coli cells as fusion proteins (entire article; abstract). Davis's fusion further possessed a N-terminal histidine tag that is used in the purification of proteins or desired protein fragments (domains) with full biological activity (entire article; abstract). Davis further uses PCR method of amplification and cloning methods for generating the expression vectors (entire article; p.383, col.1). Unless reasons to believe other wise, Davis's vectors are capable of encoding a fusion protein gene comprising a SNUT tag.

Ton-That teaches PCR amplification, cloning in expression vectors and expression of the recombinant Sortase in bacterial cells (entire article; p.9876, col.2 bridging p.9877).

Thus it would have been obvious to one of skill in the art to produce soluble fusion proteins of interest in Davis's vectors and further add fusion peptide tags of desired protein or its fragments that are capable of being expressed including that of a recombinant Sortase gene to produce as fusion peptide that is soluble. One of skill in the art would have added the coding sequences for polypeptide tag moiety with known specific binding properties (such as sortase) fused to the coding sequences of the protein of interest in order to aid in the affinity purification of the expressed protein. One of skill in the art would have a reasonable expectation of success as the art teaches that it is routine to produce fusion proteins that are soluble and further add a tag of a peptide or protein that has known, specific binding properties for aiding in immobilization and/or purification. Thus the invention as claimed is prima-facie obvious.

Conclusion:

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna Ph.D.,* whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.,* may be reached at **(571) 272-0739.** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

/ROBERT M KELLY/

Primary Examiner, Art Unit 1633